Re-evaluation Note REV2013-18

Proposed Approach to Special Reviews – Consultation Document

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1.0 Introduction

In Canada, pest control products, or pesticides, are regulated by Health Canada's Pest Management Regulatory Agency (PMRA) on behalf of the Minister of Health and under the authority of the *Pest Control Products Act*. The *Pest Control Products Act* prescribes both pre-market and post-market assessment of pesticides to determine the acceptability or continued acceptability of the health and environmental risks and value of a product for registration in Canada. Special review is one of the post-registration processes provided for under the *Pest Control Products Act*.

This document outlines the legislative requirements for special reviews as set out in the *Pest Control Products Act* as well as presents the proposed approach to special reviews.

2.0 Legislative Requirements for Special Reviews under the *Pest Control Products Act*

The *Pest Control Products Act* requires the PMRA to initiate a special review of a registered pest control product when there are reasonable grounds to believe that the health or environmental risks of the product are, or its value is, unacceptable, or when an Organisation for Economic Co-operation and Development (OECD) member country prohibits all uses of an active ingredient for health or environmental reasons. Once the above triggers have been met, the *Pest Control Products Act* requires that a science-based approach be applied in evaluating the identified risks, and in determining whether those risks are acceptable. The evaluation will be targeted to address the aspect(s) of concern related to the pest control product that prompted the special review.

Before making a final regulatory decision, a public consultation will be carried out on the proposed decision including any proposed risk management measures. Following the publication of a final regulatory decision for a special review, any person may file a Notice of Objection. The Notice of Objection must be filed within 60 days of the decision date.

Triggers for Initiating Special Reviews

Section 17 of the *Pest Control Products Act* describes the conditions under which the Minister is obligated to initiate a special review.

- Under subsection 17(1), if the Minister has reasonable grounds to believe that the health or environmental risks of a registered pest control product are, or its value is, unacceptable, a special review is initiated.

> ***ss. 17.*** *(1) The Minister shall initiate a special review of the registration of a pest control product if the Minister has reasonable grounds to believe that the health or environmental risks of the product are, or its value is, unacceptable.*

- A federal or provincial government department or agency may provide information that relates to the health or environmental risk, or the value, of a pest control product. If after considering the information provided, the Minister has reasonable grounds to believe that the health or environmental risks of a registered pest control product are, or its value is, unacceptable, a special review is initiated.

> ***ss. 17.*** *(3) Without limiting the generality of subsection (1), the Minister shall initiate a special review of the registration of a pest control product if a federal or provincial government department or agency has provided information to the Minister that relates to the health or environmental risks or the value of the product and if, after considering the information provided, the Minister has reasonable grounds to believe that the health or environmental risks of the product are, or its value is, unacceptable.*

In addition, under section 14 of the *Pest Control Products Act*, after considering any information reported under the additional information (section 12 of the *Pest Control Products Act*) or mandatory reporting (section 13 of the *Pest Control Products Act*) provisions of the *Pest Control Products Act*, the Minister must determine whether a special review should be initiated. A special review will be initiated if the Minister has reasonable grounds to believe that the health or environmental risks of the pest control product are, or its value is, unacceptable.

> ***s. 14.*** *After considering any information reported under sections 12 or 13, the Minister shall determine whether a special review of the registration of the pest control product should be initiated.*

However, under subsection 17(2) of the *Pest Control Products Act*, initiation of a special review is required:

- if an OECD member country prohibits all uses of an active ingredient for health or environmental reasons.

> ***ss. 17.*** *(2) Without limiting the generality of subsection (1), when a member country of the Organization for Economic Co-operation and Development prohibits all uses of an active ingredient for health or environmental reasons, the Minister shall initiate a special review of registered pest control products containing that active ingredient.*

Any person may request a special review through a request made to the Minister in the form and manner prescribed.[1] The reasons for requesting a special review must be relevant to registered Canadian uses and, if based on subsections 17(1) or 17(3), must include scientific information relating to health or environmental risks or to the value of the product. If subsection 17(2) is the reason for the special review request, the requestor must indicate the applicable decision from an OECD member country that prohibits all uses of an active ingredient for health or environmental reasons.

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[1] The Special Review Request Form will be made available on the Pesticides and Pest Management portion of Health Canada's website at www.hc-sc.gc.ca/cps-spc/pest/registrant-titulaire/form/index-eng.php or may be requested through the Pest Management Information Service.

3.0 Proposed Approach to Special Reviews

This proposal describes a step-by-step approach where the depth of and length of time to conduct a special review would be dependent on the complexity of issues associated with a given pest control product as well as the amount of information requiring assessment.

Step 1: Preliminary analysis
Step 2: Announcement of Special Review
Step 3: Science-based assessment of the aspect(s) of concern
Step 4: Proposed decision and consultation
Step 5: Final regulatory decision and implementation

Step 1 – Preliminary Analysis

The PMRA will carry out a preliminary analysis of the information provided in order to determine whether a special review is warranted. The purpose of the preliminary analysis phase is to determine the basis for which a special review is considered (in other words, whether it is based on a prohibition in an OECD member country or information provided from other sources). Furthermore, in most cases it is important to determine early in the process the aspect(s) of concern that warrant further investigation, as well as to identify what additional information may be required from registrants.

Regulatory decisions by an OECD member country:
Before a special review is initiated on the basis of an OECD member country's decision to prohibit all uses of an active ingredient, a preliminary analysis of the decision is necessary to confirm that it meets the conditions prescribed under subsection 17(2):

- The decision is from a member country of the OECD;
- All pest control product uses relating to the active ingredient have been prohibited; and,
- The prohibition is based on health or environmental reasons.

If the above conditions are met, a special review will be initiated.

Other Potential special reviews:
In all of the scenarios other than where there is an applicable OECD decision, the information provided or reported will be analysed before a decision as to whether a special review will be initiated. This preliminary analysis will determine whether there are reasonable grounds to believe that the health or environmental risks of a registered pest control product are, or its value is, unacceptable. Consequently, the PMRA will consider relevant information relating to the aspect(s) of concern.

A special review will be initiated if the preliminary analysis indicates that there are reasonable grounds to believe that the health or environmental risks of a registered pest control product are, or its value is, unacceptable. A special review may not be initiated, for example, if the aspect(s) of concern is not applicable to the Canadian situation or the pest control product(s) is not registered in Canada.

Step 2 – Announcement of Special Review

When a special review is required based on the preliminary analysis, an announcement will be published. If considered necessary, the PMRA will require the registrant to provide information relating to the aspect(s) of concern under special review. In addition, the PMRA will request that other federal/provincial government departments and agencies provide available information relevant to the aspect(s) of concern subject to special review.

Step 3 – Science-based assessment on the aspect(s) of concern

The aspect(s) of concern that prompted the special review will be evaluated, as required by subsection 18(4) of the *Pest Control Products Act*. A scientifically based approach will be used for evaluating the aspect(s) of concern related to the pest control product that prompted the special review.

A registration may be cancelled or amended at any time during the course of the special review if the Minister has reasonable grounds to believe that the cancellation or amendment is necessary to deal with a situation that endangers human health or safety or the environment.

Step 4 – Publish a proposed special review decision and consult the public

Upon completion of the assessment (Step 3), the PMRA will publish a proposed decision for consultation. The purpose of the consultation is to invite comments from the public and stakeholders for consideration by the PMRA prior to issuing the final special review decision.

Step 5 – Publish a final special review decision

After considering any comments received, the PMRA will publish a final decision statement.

4.0 Next Steps

The PMRA will accept written comments up to 30 days from the date of publication of this document. Please forward all comments to the PMRA Publications group (please see contact information on the cover page of this document).

Any comments received on this proposal will be considered and the PMRA will then publish a Regulatory Directive on the final approach for special reviews.